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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 12122003

Application Number: 09/421,106
Filing Date: October 15, 1999
Appellant(s): BYRUM, JOSEPH R.

Rachel L. Adams and Holly L. Prutz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 6, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: claims 1-9, 16, and 19-24 are unpatentable under 35 U.S.C. 101 as not being supported by a specific or *substantial* asserted utility or a well established utility.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-9, 16, and 19-24 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-9, 16, and 19-24 are rejected under 35 U.S.C. 101. This rejection is set forth in prior Office Action, mailed on March 7, 2003.

Claims 1-9, 16, and 19-24 are rejected under 35 U.S.C. 112, first paragraph. This rejection is set forth in prior Office Action, mailed on March 7, 2003.

(11) Response to Argument

Appellant's arguments drawn to the above rejections are noted, however, are not found persuasive for the following reasons.

9.A – Appellant summarizes a portion of *Brenner v. Manson* which includes the allegation that Appellant has met their part of the bargain in that the claimed nucleic acid molecules supply the benefit to the public of the ability to identify the presence or absence of a polymorphism in a population of soybean plants. Appellant further allege that this is a specific and substantial "real world" benefit. In response, a myriad of polymorphisms are known to occur in nucleic acid molecules in plants etc., both of the silent type as well as those which result in significant phenotypic effects. Appellant has not set forth any information which specifies whether polymorphisms, if detected via the instantly claimed invention, via hybridization, for example, correlates with anything of significance whatsoever. Thus, there is neither a specific nor substantial utility for such polymorphism detection. Further research would be required to determine what said detection of polymorphism indicates. This need for further research also supports the lack of currently available form of utility.

Appellant then argues that Appellants have produced an adequate description of the claimed nucleic acids which would demonstrate that Appellant had possession of the claimed invention. Appellant states that for each genus of claimed nucleic acid molecules, *i.e.,* the nucleic acid molecules comprising the nucleic acid sequences of SEQ ID Nos: 1-10 and their complements, has been described by recitation of the common structural feature which distinguishes molecules in the genus from molecules not in the claimed genus. In response, it should be noted that SEQ ID Numbers 1-10 do not contain a complete open reading frame. If it were so, Appellant would have indicated. Because claims are drawn to using a nucleic acid having (or comprising) a nucleic acid sequence of SEQ ID NOS: 1-10, vectors comprising them, such claim language would embrace a full-length cDNA (containing a complete open reading frame), rendering the claimed genus ill-described.

9.B – Appellant summarizes the lack of utility rejection and alleges that this is erroneous in the first paragraph in this section. This argument is an allegation without arguing the specifics of the rejection and thus non-persuasive and reasonably an introductory summary by Appellant.

Appellant argues that the lack of utility analysis misstates the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility." This argument is again an allegation without arguing the specifics of the rejection and is thus non-persuasive and reasonably an introductory summary by Appellant.

Appellant summarizes a test for utility directed to an "identifiable benefit." This does not contain an argument and thus is non-persuasive.

Appellant argues that identifiable benefits are available in the identification of polymorphisms and for expression profiling. Specification citations are pointed to and each discussed as follows. In the specification at page 47, line 17 through page 54, line 16, the discussion begins with a polymorphism statement indicating that association with a phenotype, or predisposition to a phenotype is part of the analysis thereof. The remainder of the pointed to section summarizes ways of polymorphism detection but lacks a description of any specific or substantial phenotypic association or even predisposition regarding any claimed nucleic acid. This lack of such association can only be remedied, if such an association with any phenotype even exists for the instantly claimed nucleic acids, by further research. It is also unknown what such research may or may not find regarding the instantly claimed nucleic acid molecules. This supports the lack of a currently available utility for the instantly claimed invention as is the basis for the lack of utility rejection against the instant claims. Then in the specification at page 54, lines 17-26, the marker utility is alleged for the instant invention. Procedures for marker usage are described on page 54-58 including expression profiling but without any association or even vague connection to the instantly claimed invention. Thus these generic procedural guidelines lack specificity as well as substantiality regarding the utility of the instantly claimed invention which is directed to a particular set of nucleic acids and therefore non-persuasive.

9.B(1) – Appellant argues that additional utilities are disclosed such as via sense or antisense inhibition which can then be used to screen for herbicides or plant traits such as biochemical processes and point to the specification at page 77, line 8 though page 78, line 11. Analogous to the above specification citation these citations summarize biotechnology procedures, n this case, directed to plant transformation with sense and antisense nucleic acid(s)

and analysis thereof, which may or may not have resultant effects, none of which have been determined, if they even occur, for any of the claimed nucleic acids. Appellant refers in a footnote to a section of the MPEP at page 2100-32. Consideration of said section reveals that treating or analyzing unspecified disorders or conditions lack specific and/or substantial utility as well as general treatments or analyses. This supports the lack of utility rejection against the instant claims in that unspecified analyses are only alleged. Even the cell-based assay as argued is not asserted to be directed to any specified determination but is general in nature and lacks patentable utility as also supported by said MPEP citation. Appellant refer to three other footnotes, upon consideration also describe various possible analyses but without connecting any specific or substantial utility to any of the claimed nucleic acid molecules.

9.B(1)(a) – Appellant again in this section points to polymorphism identification as an asserted utility and point again to pages 47-54 of the instant specification. This section of the specification has been responded to above as being non-persuasive.

Appellant argues that the disclosed utilities are directly analogous to the utilities of a microscope to locate and measure nucleic acids within a sample, cell, or organisms, and also indicates a comparison to gas chromatographs, etc. In response, a microscope, a gas chromatograph, etc. have well established utilities where known analyses are available with a clearly useful result. A microscope, for example, is a well known diagnostic tool for cancer detection in biopsy samples. A gas chromatograph is well known to be useful for detection of toxic material, for example, as also summarized by Appellant in the footnote of page 8 of said Brief. These uses are well known and beneficial in that results are already determined which are useful for at least one analysis type. No comparable well known use(s) have ben set forth or are

known for the instantly claimed invention. No already determined analysis result is known for the instantly claimed invention. Only further research, may, not necessarily, but ~~may~~ result in some determinable result which is beneficial. Thus, the microscope etc. is not analogous to the instant invention as there is no well known use(s) for the instant invention other than for further research to find a use thus supporting the lack of utility rejection.

Appellant argues regarding the gas chromatograph which has been responded above. Appellant then argues that the absence of a polymorphism demonstrates a common genetic heritage between two populations. In response, genetic heritage is well known to be determined via significantly large profiles of many polymorphic sites, a single polymorphism being insufficient. Thus, Appellant's allegation of this utility being in currently available form is non-persuasive. Even if a particular single polymorphic site may be a minimal suggestion of a common heritage, this has neither been investigated nor established by the instant disclosure for any of the claimed nucleic acid molecules. Thus, this is an allegation without factual support and therefore also non-persuasive.

9.B(1)(b) – Appellant argues that the claimed nucleic acids may be utilized for the isolation of nucleic acid molecules of other plants an organisms and cites the specification at page 33, lines 8-24. In response, this is an allegation without factual support and therefore non-persuasive. Appellant's disclosure has failed to provide any association or similarity between such other plants or organisms that would indicate whether or not such isolation is reasonably available.

Appellant attempts to attribute utility to the claimed nucleic acids through the use of a golf club analogy. The golf club is useful and has utility in hitting a golf ball, and not an

unknown object. Appellants are attempting to argue that because a specific nucleic acid which has patentable utility serves to give patentable utility to ***all nucleic acids***. Such correlation is incorrect. For example, a nucleic acid is determined to have a patentable utility based on its ability to diagnose a person's predisposition to a cancer. However, this finding would not imply that any piece of nucleic acid now has a patentable utility. Appellants have not disclosed any utility to which the claimed nucleic acid could be substantially useful for, other than asserting that it *could* be useful for an assay to which no immediate benefit has been disclosed.

Appellant argues that isolation of a promoter is an example of a disclosed utility. In response, there is no indication of what utility results or is promoted, even if a promoter was isolated by the chromosome walk, as argued by Appellant. Further research would be required to characterize such a promoter as to what may or may not activate it. Thus, again further research would be required to define a specific and/or substantial utility for the claimed nucleic acid molecules which supports this lack of utility rejection.

9.B(2) – Appellant summarizes some legal issues regarding "substantial" utility but no argument is apparent therein.

Appellant argues that the claimed nucleic acid molecules would provide an immediate benefit to the public in form of a high-throughput microarray analysis of expression changes in a series of tissue samples. However, there is no disclosure as to why a skilled artisan would use the claimed nucleic acids and for what purpose, other than to conduct further research to arrive at the immediately apparent use. For example, the instant specification lacks any disclosure as to why a skilled artisan in the field of plant genetics would be inclined to employ the claimed nucleic acids over other nucleic acids which are isolated from soybeans. The skilled artisan

would have to conduct further research on the claimed nucleic acids in order to determine why such nucleic acids should be employed in a microarray to assay for a specific trait. The instant specification lacks such information.

Appellant argues that a multi-million dollar industry has been established for ESTs which may also find utility as industrial products for fermentation processes. In response, there is no instant support for the instantly claimed nucleic acid molecules being of monetary value. For fermentation utility, some type of specific and substantial fermentation usefulness would be required. No such specific or substantial utility has been even asserted for fermentation usage. Further research again would be required to determine the result of the presence of the instantly claimed nucleic acid molecules in fermentation processes, such as in bacteria or plants being fermented. This need for further research again supports the lack of utility rejection.

Appellant argues that the market participants for EST products are primarily sophisticated corporations with highly knowledgeable scientists. In response, no market value has been determined or even alleged for the instantly claimed nucleic acids. Thus, the allegation of such value is without factual support and non-persuasive. It is also pointed out that ESTs in such markets are valued in large sets of ESTs and not singly unless some specific and substantial utility for a particular EST is known. Thus, the instantly claimed nucleic acid molecules do not correspond to such large sets of ESTs as sold either in sequence information form or as combinatorial sets thus making this argument non-persuasive.

9.B(3) – This section argues that the credibility issues is generally directed to "hare-brained" utilities or wholly inoperative inventions. In response, the lack of utility rejection is based on a lack of either a well established utility or a specific, substantial, and credible utility

with credibility not being assessed. It is acknowledged that polymorphism analysis, for example, are credible utilities, but that a lack of utility still exists if there is no well established utility or either a specific or substantial utility as is the situation for the instantly claimed invention.

9.C – Appellant argues that the instantly claimed invention is enabled due to having met the utility requirements as set forth above. No further argument(s) are set forth other than those responded to above as being non-persuasive. Therefore, the rejection is maintained for the reasons already described above for the lack of utility rejection.

9.D – Appellant states that Appellants need not describe every nuance of the claimed invention when using the transitive language, "comprising." Appellants continue that the specification demonstrates to one skilled in the art that Appellant was in possession of the claimed general of nucleic acid molecules. Appellants specific arguments are produced in the following section 9.D(1).

9.D(1) and (2) – Appellants argue that they have provided the nucleic acid sequence required by the claims, *i.e.,* SEQ ID NOS: 1-10, vectors comprising these nucleotide sequences, and bacterial artificial chromosomes comprising these nucleotide sequences, and therefore have established possession of the claimed invention. The claimed invention, which is drawn to a polynucleotide *comprising* the above SEQ ID Numbers, when the specification only discloses a partial sequence, as well as partial open reading frame, effectively encompasses a full-length cDNA sequence comprising a full open reading frame. While it is acknowledged that Appellant need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid

molecules being claimed embraces any and every type of nucleic acid molecule that comprises any of claimed SEQ ID Numbers, and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Appellant was not in possession of genomic materials that contain the common EST fragment, which are embraced by the open-ended claims.

Additionally, one skilled in the art would reasonably conclude that the claims embrace full length mRNAs, cDNAs and genomic sequences, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising the claimed SEQ ID Numbers, and no other indication that would suggest Appellant possessed them. This particular subgenus embraced by the claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode a corresponding protein(s).

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Appellants and the Examiner disagree is whether the disclosure of a partial sequence of nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence.

As stated in *University of California v. Eli Lilly and Co.* at page 1404:

> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

That Appellants claims embrace nucleic acid molecules that encode a corresponding protein, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.,* at page 1405, further noted regarding generic claims:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe* , 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

In the instant case, the only species specifically enumerated are the nucleic acid molecules of SEQ ID Numbers 1-10. The specific embodiments that in addition to these sequences include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence ***has not been*** disclosed. Clearly, the specification would not show one skilled in the art that the these desired subcombinations were possessed by Appellant, and thus the embracing genus was also not possessed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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December 15, 2003

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